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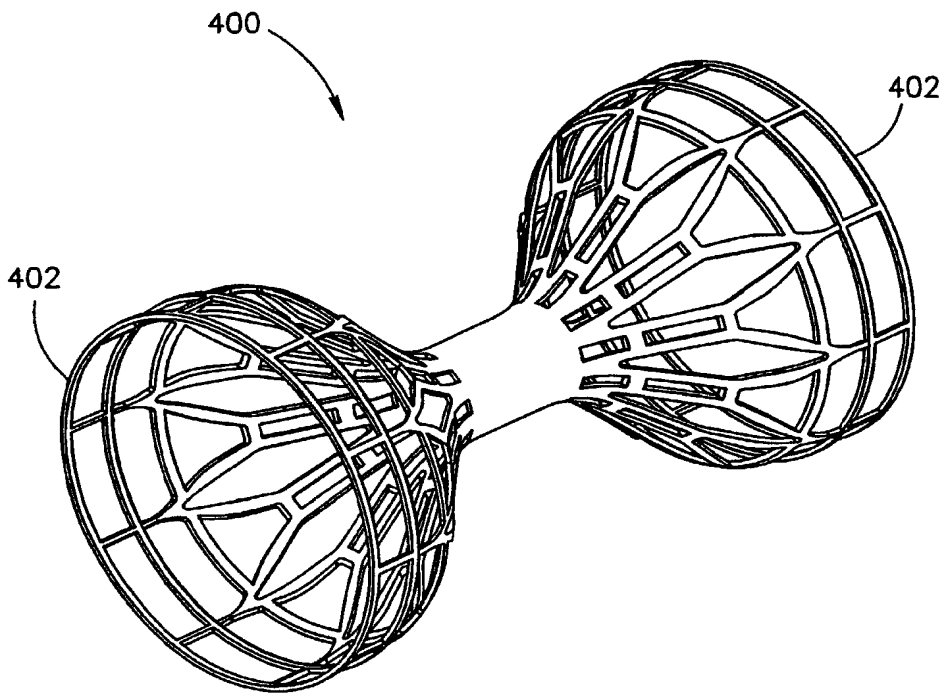

(57) Abstract: A reducer implant for insertion in a blood vessel, for reducing an inner diameter of said vessel and flow therethrough, having at least one narrowed section having a first diameter; and at least one flared section having a diameter substantially greater than said first diameter. Optionally, the reducer is formed of a material and has a geometry that does not cause coagulation of blood in its vicinity.

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NARROWING IMPLANT

RELATED APPLICATIONS

This application is related to US application serial number 09/534,968, filed March 27, 2000 the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to devices for narrowing bodily conduits, for example, blood vessels, to less than their normal diameter.

BACKGROUND OF THE INVENTION

The heart pumps blood through the body. The heart itself is fed by coronary arteries that end at capillaries. The capillaries are drained by a network of coronary veins, that (typically) flow into a vein known as the coronary sinus. The coronary sinus is a short, large diameter vein that is substantially contiguous with a right atrium, the atrium that collects all venous blood from the body.

Occlusion of coronary arteries is a leading cause of death, especially sudden death, in what is commonly called a "heart attack". When blood flow to a portion of the heart is suddenly stopped, the portion becomes ischemic and its electrical activity is disrupted. As the activity of the heart is mediated by electrical signal propagation, such disruption typically propagates to the rest of the heart, disorganizes the heart's activation and causes the heart output to be reduced drastically, which leads to ischemia and death of the brain. In addition, the disorganized activity often damages the heart beyond what was caused directly by the blockage.

If a patient survives the direct effects of the heart attack, the damage to the heart may predispose the patient to future electrical disorders and/or may significantly reduce the cardiac output, thus reducing quality of life and life expectancy.

Angina pectoris is a chronic or semi-chronic condition which, while not life-threatening, significantly reduces quality of life. In general, the heart responds to increased demand by working harder, requiring more coronary blood flow. When coronary arteries are stenosed or occluded, the increased blood flow cannot be provided, and pain, caused by the resulting ischemia, is produced.

The heart has natural mechanisms to overcome stenosis in coronary arteries. One such mechanism is angiogenesis, in which new arteries are created, for bypassing the stenosis.

Since angiogenesis does not always occur naturally, various procedures have been suggested to encourage it. For example Trans-Myocardial Revascularization (TMR), is a process in which multiple holes are drilled in the heart, with the intent of causing new vessels to be created.

Beck, in "The Surgical Management of Coronary Artery Disease: Background, Rationale, Clinical Experience" by C.S. Beck and B. L. Brofman, 1956, by the American College of Physicians in Annals of Internal Medicine Vol. 45, No. 6, December 1956 and in "Long Term Influence of the Beck Operation for Coronary Heart Disease", by B. L. Brofman in the American Journal of Cardiology August 1960, the disclosures of which are incorporated herein by reference, performed open chest surgery in which a coronary sinus vein was restricted, by an external suture. After a few months, coronary blood supply apparently improved. However, this method has fallen in disfavor, in part probably due to the need to open the chest and lift up the heart, to reach the coronary sinus vein.

A standard treatment of stenosed arteries is inserting a stent into the artery, at the stenosed point. The stent, for example a metal coil or mesh, is expanded to have an inner diameter similar to that of the original stenosed blood vessel. If many stenoses are present, it is not common to implant multiple stents. Instead, a bypass procedure, in which a conduit is used to bypass the stenoses, is performed.

US patent 5,618,301, the disclosure of which is incorporated herein by reference, describes a stent-like device for reducing the diameter of a body conduit. What is described is an open mesh stent that can be inserted in a stented channel created by a TIPS (Trans-Jugular Intra-Hepatic Portal-Systemic Shunt) procedure, to reduce the blood flow rate through the channel. In order to ensure the flow diameter is reduced and prevent flow through the open mesh, a plurality of thromobogentic threads are provided on the outside of the mesh. However, as can be appreciated, intentionally forming thrombosis in most any part of the vascular system, and especially near the heart, can lead to propagating coagulation or floating thromboses, which are potentially fatal.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to a diameter reducing implant adapted for insertion into blood vessels. In an exemplary embodiment of the invention, the implant (reducer) includes at least one narrowed lumen portion, for limiting blood flow. In an exemplary embodiment of the invention, the reducer is designed to not cause blood coagulation outside of the narrowed blood flow. The reduced diameter may, for

example, reduce total blood flow through the implant or change the temporal profile of such flow and/or temporal profile of pressure in the vessel.

In an exemplary embodiment of the invention, the reducer is designed not to damage vessel walls, for example, artery walls or vein walls. In one example, the reducer edges are curled. Alternatively or additionally, the reducer edges are coated with a soft coating. Alternatively or additionally, the reducer edges extend parallel to the vessel. Alternatively or additionally, the elasticity of the reducer is low, to prevent undue pressure on the walls.

In an exemplary embodiment of the invention, the blood vessel is a coronary vein or a coronary sinus. Optionally, the narrowing reduces the vessel cross-section by 30%, 50%, 80%, 90% or any other lower, larger or intermediate amount, or even completely occludes the vessel. It should be noted that the heart generally has additional drainage paths besides the coronary sinus, so that even complete occlusion of the coronary sinus will not generally prevent blood from reaching the coronary capillaries. For example, the narrowing may have an inner diameter of 1 mm, 2 mm, 3 mm or any larger, smaller or intermediate size. Optionally, the unexpanding reducer is between 10 mm and 80 mm long. Optionally, the reducer is asymmetric, for example, adapted to fit the normal shape of the coronary sinus.

In an exemplary embodiment of the invention, the reducer includes one or more narrowed sections and one or more un-narrowed sections. In an exemplary embodiment of the invention, narrowing sections are non-expandable, expand less or require a greater force to cause them to expand, as compared to un-narrowed sections. In an exemplary embodiment of the invention, the un-narrowed sections expand a considerable amount, for example a factor of 2, 3, 4 or 5, or any greater, smaller or intermediate factor, in diameter, from their diameter during insertion.

In an exemplary embodiment of the invention, the narrowed sections comprises a ring. Optionally, the ring defines a mesh to allow some expansion thereof. Optionally, after a reducer is deployed, the ring may be further expanded, to reduce the degree of narrowing.

In some embodiments of the invention, the vessel walls collapse or are urged to collapsed onto the reducer. Alternatively, in some embodiments of the invention, a coagulation-encouraging material or threads are provided outside the narrowed portion (i.e., between the portion and the vessel wall) to encourage the formation of clots between the reducer body and the vessel wall.

Optionally, the reducer is coated with a flexible coating (inside and/or out) and/or defines a dense mesh pattern, that prevents or reduces blood flow through the reducer

surface, for example, forcing at least 40%, 60%, 80%, 90% or any smaller, greater or intermediate flow percentage to be through an axial lumen defined by said reducer. In an exemplary embodiment of the invention, the dense mesh fills at least 30%, 40%, 60%, 70%, 80% or any greater, smaller or intermediate percentage of a surface of the reducer.

In an exemplary embodiment of the invention, the reducer comprises a rim, which rim is constructed to be more difficult to expand (for plastic) or expand less (for self-expanding) than portions of the reducer just inside the rim. Thus, when the reducer is expanded, the rim does not flare out and an inwards curving or a parallel profile is achieved in the reducer. Optionally, the rim defines a maximal radius of the rim, to prevent over expansion of the rim of the reducer.

In an exemplary embodiment of the invention, the reducer is a plastically deformed reducer, expanded using a balloon. In an exemplary embodiment of the invention, in order to prevent the balloon from catching in the narrowed section of the reducer, the balloon comprises a plurality of fingers on its outside, so that the fingers can bend back and be pulled out through the narrowing. Alternatively or additionally, the fingers are asymmetric, so that when the balloon deflates, the balloon will twist closed.

An aspect of some embodiments of the invention relates to a method of installing a narrowing device. In an exemplary embodiment of the invention, the narrowing device is installed in a coronary sinus vein (hereafter "coronary sinus"). Alternatively or additionally, the narrowing device is installed in one or more coronary veins, for example the great coronary vein. In an exemplary embodiment of the invention, a delivery catheter is inserted through a central vein, such as the Jugular vein and brought to the coronary sinus. The reducer is released from the delivery catheter and allowed to elastically expand and/or is plastically expanded using a balloon. Optionally, a pressure sensor is provided on the delivery catheter for assessing the effect of the reducer on the venous pressure before the reducer and/or after the reducer.

An aspect of some embodiments of the invention relates to a method of selecting a reducer. In an exemplary embodiment of the invention, functional information on the heart is used to assess need. An image, such as an echo-cardiography image, a Doppler image or a CT image is used to measure the coronary sinus (or any other target vein). The size of the reducer and its degree of narrowing are then selected to match the geometry of the coronary sinus and/or the desired therapeutic effect.

There is thus provided in accordance with an exemplary embodiment of the invention, a reducer for insertion in a blood vessel, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter at least 20% greater than said first diameter,

wherein said reducer is formed of a material and has a geometry that does not cause coagulation of blood in its vicinity. Optionally, said reducer is operative to increase a coronary artery blood pressure when inserted in a coronary vein. Optionally, said reducer is operative to modify a coronary artery blood flow distribution when inserted in a coronary vein. Optionally, said reducer is operative to increase a coronary sinus blood pressure when inserted in a coronary sinus. Optionally, said reducer is operative to increase an intra-myocardial perfusion when inserted in a coronary sinus.

In an exemplary embodiment of the invention, said flared section includes at least one area adapted to contact a wall of a vein. Optionally, said area is made large enough to prevent damage to the wall. Optionally, said area has an axial extent of at least 2 mm. Optionally, said area has an axial extent of at least 4 mm.

In an exemplary embodiment of the invention, said flared section has an outside edge. Optionally, said outside edge lies on a single plane. Alternatively or additionally, said outside edge is defined by a plurality of elongate sections that cooperate to define a maximal rim for said reducer. Alternatively or additionally, said outside edge is smooth. Alternatively or additionally, said outside edge is curved inwards towards an axis of said reducer. Alternatively or additionally, said outside edge is coated with a soft material.

In an exemplary embodiment of the invention, said reducer doesn't cause turbulence inside a lumen defined by said narrowed section and said flared section. Alternatively or additionally, said narrowed section comprises a ring segment having a different surface design from flared section. Alternatively or additionally, said narrowed section comprises a solid ring.

In an exemplary embodiment of the invention, said narrowed section comprises an array of cell elements.

In an exemplary embodiment of the invention, said reducer is expanded, after insertion, from an unexpanded configuration to an expanded configuration. Optionally, said flared section is plastically deformable to provide said configuration change. Alternatively said flared section is self-expanding to provide said configuration change.

In an exemplary embodiment of the invention, said narrowed section self-expanding to provide said configuration change. Alternatively, said narrowed section is plastically deformable to provide said configuration change. Alternatively, said narrowed section does not expand. Alternatively, said narrowed section is further expandable after said reducer is in said expanded configuration.

In an exemplary embodiment of the invention, said reducer comprises a ring mounted outside of said narrowed section, said ring defining a maximal diameter of said narrowed section.

In an exemplary embodiment of the invention, said narrowed section is formed of a pliable material. Alternatively or additionally, said reducer is formed of at least one of an elastic material, a shape-memory material and a super-elastic material.

In an exemplary embodiment of the invention, different parts of said reducer have different degrees of resistance to deforming. Optionally, said narrowed section has a greater resistance to deformation than said flared section. Alternatively, a rim area of said flared section has a greater resistance to deformation than an adjacent part of said flared section.

In an exemplary embodiment of the invention, said narrowed section has an axial extent of between 1 mm and 5 mm.

In an exemplary embodiment of the invention, said reducer has an axial extent of between 10 mm and 30 mm.

In an exemplary embodiment of the invention, said narrowed section has a cross-sectional area of less than 70% of a maximum cross-sectional area of said flared section. Optionally, said narrowed section has a cross-sectional area of less than 50% of a maximum cross-sectional area of said flared section. Optionally, said narrowed section has a cross-sectional area of less than 40% of a maximum cross-sectional area of said flared section. Optionally, said narrowed section has a cross-sectional area of less than 30% of a maximum cross-sectional area of said flared section. Optionally, said narrowed section has a cross-sectional area of less than 20% of a maximum cross-sectional area of said flared section.

In an exemplary embodiment of the invention, said flared section has an axial extent of between 4 mm and 10 mm.

In an exemplary embodiment of the invention, said reducer is adapted for insertion in a human coronary sinus. Alternatively or additionally, said reducer is adapted for insertion in a human coronary vein. Optionally, said adaptation is by size.

In an exemplary embodiment of the invention, said at least one flared section comprises at least two flared sections.

In an exemplary embodiment of the invention, said reducer describes an hourglass figure.

In an exemplary embodiment of the invention, said flared section is dense, to reduce blood flow therethrough. Alternatively or additionally, said flared section is coated, to reduce blood flow therethrough.

In an exemplary embodiment of the invention, said reducer is formed of a soft material, to reduce contact force against an enclosing vessel wall.

In an exemplary embodiment of the invention, said reducer is operative to release a slow release molecule after it is deployed.

In an exemplary embodiment of the invention, said reducer has an outside surface adapted to attach to a wall of a vein.

In an exemplary embodiment of the invention, said narrowed section comprises a valve.

There is also provided in accordance with an exemplary embodiment of the invention, a reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter at least 20% greater than said first diameter,

wherein said reducer is adapted to be plastically deformed from a first configuration in which said reducer is unexpanded to a second configuration in which said reducer is expanded. Optionally, said narrowing section has a length of at least 10% of a total axial length of said reducer. Optionally, said narrowing section has a length of at least 20% of a total axial length of said reducer.

There is also provided in accordance with an exemplary embodiment of the invention, a reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter greater than said first diameter,

wherein said reducer is adapted to contact a vein at said flared section. Optionally, said adaptation comprises forming said flared section to reduce a probability of damage to said vein. Alternatively or additionally, said adaptation comprises forming said reducer of a soft material to reduce a contact force between said reducer and said vein.

In an exemplary embodiment of the invention, said reducer is adapted to cause coagulation in an area defined between said reducer and a wall of said vein.

There is also provided in accordance with an exemplary embodiment of the invention, a reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter at least 20% greater than said first diameter,

wherein said flared section is resistant to blood flow across a wall of said section, such that at least 50% of blood flow through the reducer passes through a lumen defined by said flared section and said narrowed section. Optionally, at least 80% of blood flow through the reducer passes through a lumen defined by said flared section and said narrowed section. Optionally, at least 90% of blood flow through the reducer passes through a lumen defined by said flared section and said narrowed section.

There is also provided in accordance with an exemplary embodiment of the invention, a reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter substantially greater than said first diameter,

wherein said flared section and said narrowed section cooperate to substantially reduce blood flow through a lumen defined by said sections, relative to flow through a cylinder having a maximal diameter of the flared section

There is also provided in accordance with an exemplary embodiment of the invention, a blood vessel reducer delivery kit, comprising:

a guide catheter;

a plastically deformable reducer having an hour-glass figure when deformed and adapted to ride on said catheter; and

a balloon having an inflation profile matching said hour-glass figure.

There is also provided in accordance with an exemplary embodiment of the invention, a method of reducer selection, comprising:

determining a desired hemodynamic effect in a coronary vascular system; and

selecting a reducer having a suitable geometry to achieve said desired hemodynamic effect, from a set of reducers of different geometries. Optionally, said desired effect is at least one of: increase in myocardial perfusion pressure, increase in myocardial pressure, increase

in myocardial perfusion duration, increase in coronary artery pressure, redistribution of blood flow in coronary arteries, increase in pressure in a coronary sinus and/or a restarting of a coronary artery autoregulation mechanism.

There is also provided in accordance with an exemplary embodiment of the invention, a method of affecting hemodynamic parameters of a coronary system, comprising:

selecting a reducer for reducing a diameter of a coronary vein; and

implanting said reducer in said coronary vein. Optionally, said coronary vein is a coronary sinus.

There is also provided in accordance with an exemplary embodiment of the invention, a kit for reducing blood flow in a venous system, comprising: a plurality of vascular implants, each defining a narrowed section, said plurality of implants including at least two implants with different geometrical properties. Optionally, said two implants have different degrees of narrowing. Alternatively or additionally, said two implants have different outer diameters, for matching different coronary veins.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the invention will be described with reference to the following description of exemplary embodiments, in conjunction with the figures. The figures are generally not shown to scale and any measurements are only meant to be exemplary and not necessarily limiting. In the figures, identical structures, elements or parts which appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, in which:

Fig. 1 is a schematic showing of a reducer installed in a coronary sinus vein, in accordance with an exemplary embodiment of the invention;

Fig. 2 is a schematic side view of a reducer, in accordance with an exemplary embodiment of the invention;

Figs. 3A and 3B illustrate a plan layout of a reducer, in accordance with an exemplary embodiment of the invention;

Fig. 3C shows illustrates the reducer of Fig. 3A in an unexpanded configuration and mounted on a delivery system, in accordance with an exemplary embodiment of the invention;

Fig. 3D illustrates a coil-based reducer, in accordance with an exemplary embodiment of the invention;

Fig. 4A and 4B show a plan layout of a reducer having a smooth rim when expanded, in accordance with an exemplary embodiment of the invention;

Fig. 4C shows a reducer with a smooth rim in an expanded configuration, in accordance with an exemplary embodiment of the invention;

Fig. 5 shows a vascular path to a coronary sinus, in accordance with an exemplary embodiment of the invention;

Fig. 6A shows a plastically deforming reducer delivery system, in accordance with an exemplary embodiment of the invention;

Fig. 6B shows a delivery system for delivering a self-expanding reducer, in accordance with an exemplary embodiment of the invention;

Fig. 6C shows a balloon design, in accordance with an exemplary embodiment of the invention;

Fig. 7 is a flowchart of a method of reducer delivery, in accordance with an exemplary embodiment of the invention;

Fig. 8 shows a portion of a plan layout of a section of a reducer with selective narrowing control, in accordance with an exemplary embodiment of the invention; and

Figs. 9A-9F illustrate various reducer variations, in accordance with exemplary embodiments of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Fig. 1 is a schematic showing of a reducer 100 installed in a coronary sinus vein 102, in accordance with an exemplary embodiment of the invention. Coronary sinus 102 drains a plurality of cardiac veins 106 into a right atrium 104. The cardiac circulation is generally hierarchical and comprises of stages of reducing (or increasing) diameter. Thus, veins 106, in turn, drain a plurality of thin venoules 108, which, after a few stages, drain a plurality of capillaries 110. Capillary 110 are fed by a plurality of arterioles 112, which, after a few stages, are fed by a plurality of coronary arteries 114 and 120. A stenosis 116 is shown in a coronary artery 114. While the cardiac circulation is generally hierarchical, some connection exists between different branches. Occasionally, the existence of stenosis 116 will cause a collateral connection 118 to spontaneously form (or widen an existing connection) between coronaries 114 and 120, bypassing stenosis 116.

In some cases, however, this spontaneous formation does not occur. In an exemplary embodiment of the invention, a reducer 100 is placed in coronary sinus 102 and has a narrowing significant enough to encourage the formation of collateral connection 118. It is

hypothesized that collateral connection 118 is caused by an increase in venous blood pressure, which, in turn, increases the pressure in the capillaries and/or causes retro-flow in the capillaries and/or causes drainage of the capillaries directly into the heart. However, even if this hypothesis is incorrect, several studies, that included numerous experiments and actual procedures have shown that constriction of coronary sinus 102 will generally cause the formation of collateral circulation and/or otherwise improve the condition of patients with blocked coronary arteries. Alternative or additional hypotheses which are optionally used to select the constrictive effect of reducer 100 include:

(a) Reducer 100 increases the pressure in the coronary capillaries, thus increasing perfusion duration.

(b) An increase in resistance of the venous system causes redistribution of blood flow in coronary arteries.

(c) An increase in resistance of venous system increases intra-myocardial perfusion pressure and/or intra-myocardial pressure.

(d) Increasing the arterial diastolic pressure (by restricting venous drainage) causes the arterial auto-regulation to start working again, for example, such an auto regulation as described in Braunwald "Heart Disease: A textbook of Cardiovascular Medicine", 5th Edition, 1997, W.B. Saunders Company, Chapter 36, pages 1168-1169.

It should be noted that the selection of reducer 100 may be made to achieve one or more of the above suggested effects, optionally to a desired degree and/or taking into account safety issues, such as allowing some drainage and maximum pressure allowed by the coronary venous drainage system. These effects may be determined using various measurements, as described below with reference to Fig. 7.

Fig. 2 is a schematic side view of reducer 100, in accordance with an exemplary embodiment of the invention. Reducer 100 comprises a narrowed section 204 and at least one funnel shaped section 200 (and 202) leading into narrowed section 204. Section 200 (and 202) includes portions 210 and 206 that are inclined relative to the wall of coronary sinus 102 and portions 212 and 208 that are parallel to the wall.

In the exemplary embodiment and measurements shown, reducer 100 is expandable and shortens somewhat during expansion: having a length of 20 mm before expansion and about 18.8 mm after expansion. Optionally, a non-shortening design is used, for example a mesh as in peristaltic stents, such as described in US patent 5,662,713, the disclosure of which is incorporated herein by reference. An exemplary material thickness is 0.15 mm,

however, thinner or thicker materials may be used. Other exemplary lengths are 5 mm, 12 mm, 24 mm, 35 mm 45 mm and any smaller, intermediate or larger size. The length is optionally selected to match a physiological size of the target vein (e.g., length and curves) and/or to ensure good contact with vein walls. The length of narrowing 204 may be, for example, 0.5 mm, 1 mm, 2 mm, 3 mm, 5 mm or any smaller, intermediate or larger length, for example selected to achieve desired flow dynamics. An exemplary inner diameter of the flared out sections is between 2 mm and 30 mm, for example, 5 mm, 10 mm, 15 mm, 20 mm or any larger, smaller or intermediate diameter, for example selected to match the vein diameter. The inner diameter of the narrowing may be, for example, 1 mm, 2 mm, 3 mm, 5 mm, 10 mm or any smaller, larger or intermediate diameter, for example selected to achieve desired flow dynamics and/or a pressure differential across the reducer.

In an exemplary embodiment of the invention, the ratio between the cross-section of narrowing 204 and the ends of reducer 100 is 0.9, 0.8, 0.6, 0.4, 0.2 or any larger, smaller or intermediate ratio, for example selected to achieve desired flow dynamics and/or a pressure differential across the reducer.

While a circular cross-section is shown, other cross-sections may be used, for example, polygonal and ellipsoid. A potential advantage of non-circular cross-sections is that the device is less likely to migrate axially. Alternatively or additionally, the outside of the reducer is roughened and/or otherwise adapted to adhere to the vein wall. The cross-section shape and/or orientation optionally changes along the length of reducer 100.

Figs. 3A and 3B illustrate a plan layout of reducer 100, in accordance with an exemplary embodiment of the invention. Fig. 3B shows a detail of the plan layout. In this plan layout, the ends of sections 200 and 202 are caused to be parallel to the vessel wall when reducer 100 is expanded.

In an exemplary embodiment of the invention, the outside rim of reducer 100 is defined by sections 340, 342 and 344, shown in Fig. 3B. Optionally, the total length of these sections defines the maximum rim length. Alternatively or additionally, the bending areas in and between these sections define the relative force required to expand the rim region relative to the area near the rim. If the rim region is more difficult to expand and/or is expanded less than the adjacent regions, the expansion of reducer 100 will tend to cause the rim to bend in, or at least not flare out. Alternatively, in a self-expanding reducer, the existence of sections 340, 342 and 344 can be used to endure the final shape of the rim. Optionally, additional sections 346 are provided around the circumference of reducer 100,

which define outer cells in reducer 100, which outer cells may have a maximum expansion that is the same or smaller than that nearby (axially inwards) cells. This design can also be used to control the shape of the rim.

In an exemplary embodiment of the invention, a reducer is characterized by this maximum diameter, which may be used, for example, for selecting a particular reducer to match a patient. Optionally, during expansion, the balloon is aligned with reducer 100 so that it only contacts the rim region or only contacts the non-rim regions of reducer 100.

Fig. 3C shows reducer 100 in an unexpanded configuration and mounted on a delivery system 302 (e.g., a balloon catheter).

In an exemplary embodiment of the invention, reducer 100 is formed by cutting out of a sheet of metal or a tube, for example, using laser, water cutting, chemical erosion or metal stamping (e.g., with the result being welded to form a tube). Alternatively, reducer 100 is woven (e.g. of metal or plastic fiber), for example, using methods as well known in the art. Optionally, narrowing section 204 is made using a different method from flaring sections 200 and 202, for example, the flaring sections being woven and the narrowing section being cut from sheet metal. In an alternative embodiment of the invention, reducer 100 includes with a constraining ring that prevents the expansion of narrowing section 204. Optionally, the restraining ring is plastically expandable, possibly under a higher pressure than the rest of reducer 100, which may be plastically deformable or self-expanding. Alternatively or additionally, the restraining ring is selected to set the desired degree of narrowing, and then mounted on a reducer, a stent or a stent graft, for implantation. In a sleeve reducer (Fig. 9F, below), a similar effect may be achieved by suturing the stent graft.

In an alternative embodiment, reducer 100 is cut out of a sheet and then spirally twisted around a mandrel to form the shape of reducer 100. Alternatively, reducer 100 is cut out of a tube, with the flared parts being spiral cuts and the narrowing part being a ring cut. Alternatively, reducer 100 is formed as a coil spring, with axially varying relaxation positions. Fig. 3D illustrates a coil-based reducer 320, in accordance with an exemplary embodiment of the invention.

In an exemplary embodiment of the invention, once reducer 100 is formed, it is mounted in a jig having the desired final expanded shape and heated to train that shape (e.g., for a super-elastic reducer).

In an exemplary embodiment of the invention, reducer 100 is adapted for use in a coronary sinus or other coronary vein. Veins are typified by having a low degree of elasticity

and being relatively sensitive to tears (as compared to arteries). In one example, the edges of reducer 100 are curved inwards or curled, for example as shown by reference 130 in Fig. 1. Alternatively or additionally, the edges are folded back and/or smoothed to remove sharp edges. Alternatively, the parallel sections 208 and 212 (Fig. 2) are made long enough to support reducer 100 without harming coronary sinus 102. Alternatively or additionally, reducer 100 or at least larger diameter portions thereof, is made soft enough and/or with a low spring constant, to prevent the reducer from applying too much pressure on the coronary reducer wall. Alternatively or additionally, the ends of reducer 100 are coated with a flexible coating, for example, a soft silicone elastomer or another soft plastic or rubber material such as Latex, Teflon and/or Polyurethane.

Alternatively or additionally, reducer 100 has a smooth rim at each end. Fig. 4A and 4B show a plan layout of a reducer 400 having a smooth rim 402 (when expanded).

In Fig. 4B, outer rim 402 is defined by sections 440 and 446. As shown, these sections are designed to provide a relative smooth rim, possibly with small amounts of distortion (so rim 402 remains smooth) where the sections connect to sections 442 and 444. Together, sections 442, 444 and 446 define outer cells for rim 402.

Fig. 4C shows an alternative design for reducer 400, in an expanded configuration, illustrating smooth rims 402.

Referring back to Fig. 1, a region 132 is defined between reducer 100 and the wall of coronary sinus 102. In an exemplary embodiment of the invention, it is desired that little or no blood bypass narrowing 204 through region 132. In some types of reducer 100, this is achieved by sections 200 and 202 being dense enough to slow down blood flow considerably or being practically blood-proof, for example, in a coil-type reducer. Alternatively or additionally, an elastic coating is provided on the inside or outside of reducer 100, for example, latex, to cover and prevent flow through openings in the reducer body. In an exemplary embodiment of the invention, the coating is a separate, flexible layer, that is attached to the reducer at several points (e.g., at the center and at either end, such as to prevent tearing of the layer by the expanding reducer) and is performed to the shape of the expanded reducer, prior to expansion, this coating layer is folded and/or pleated. Alternatively or additionally, one reducer is implanted inside another reducer, with misaligned mesh patterns, so that the solid parts of one reducer block apertures defined by the other reducer.

Alternatively or additionally, the walls of coronary sinus 102 collapse onto reducer 100, blocking any apertures in the body of reducer 100 and preventing flow bypassing narrowing section 204. Optionally, reducer 100 is constructed to encourage such collapsing, for example, by the pattern of apertures in funnel section 200 being different from those in funnel section 202, or by the external diameter of reducer 100 being slightly greater than that of coronary sinus 102. It should be noted that since veins are typically soft and are surrounded by tissue, veins typically collapse when their inner pressure is reduced.

Optionally, the outer surface of reducer 100 includes means for attaching the reducer to the collapsed walls, for example, small barbs, an adhesive and/or a fibrosis-formation encouraging material. Optionally, during implantation of reducer 100, flow of blood from the coronary veins to the reducer is blocked for a short period of time and/or blood in reducer 100 is sucked out, to encourage the coronary sinus walls to collapse onto reducer 100 and attached to reducer 100. Optionally, a reducer used for such a procedure can have very short flaring parts, possible with an outer diameter smaller than that of the coronary sinus.

In some embodiments of the invention, a coagulation enhancing material or geometry (e.g., thrombogenic threads) are provided in area 132, for example, being attached to reducer 100. Thus, region 132 will fill with coagulated blood and prevent further blood flow therethrough. In an exemplary embodiment of the invention, however, the reducer is made as un-thrombogenic as possible (e.g., suitable coatings and geometry, as known in the art), to prevent propagation of clots into the heart. Coagulation enhancing is optionally provided if the reducer is relatively impervious to blood flow through its walls, so that clots are not expected to propagate.

In an exemplary embodiment of the invention, reducer 100 is formed of metal, for example, a NiTi alloy (e.g., Nitinol) or stainless steel (e.g., 316L and 316LS). Alternatively, reducer 100 is formed of- or coated with- other bio-compatible materials, such as Nylon and other plastics. Optionally, reducer 100 is bio-absorbable. A reducer made of plastic can be, for example, cast or injection molded. Depending on the type of material and the processing applied, reducer 100 may be plastically deformable to the geometry shown in Fig. 1. Alternatively, reducer 100 may relax to that geometry, for example, using an elastic, shape-memory or super-elastic relaxation process.

Optionally, reducer 100 is formed of two or more materials, for example, narrowing section 204 being a ring formed of plastic and the flared sections being formed of metal.

Optionally, the delivery system includes a pressure transducer at its end, for example, for measuring base-line pressure in the coronary sinus. Alternatively or additionally, the delivery system includes a contrast injection channel, for example, for assisting in imaging the coronary sinus before, during and/or after deployment of reducer 100.

Fig. 7 is a flowchart 700 of a method of reducer delivery, in accordance with an exemplary embodiment of the invention. It should be appreciated that the procedure of Fig. 7 is an exemplary procedure and other procedures may be applied as well. In particular, the process of Fig. 7 assumes, for clarity, the use of a particular sheath-based delivery system, the use of which is not an essential feature of the invention.

In an exemplary embodiment of the invention, the coronary sinus treatment is combined with an arterial treatment, such as PCTA, stenosis removal (e.g., laser ablation) and/or stenting. The arterial treatment may be applied, for example, before, during or after the venous treatment, possibly during a same use of the catheterization facilities.

At 702, various pre-implantation tests and procedures are optionally applied to a patient to be catheterized, for example, a few weeks, a few days or a few hours before the catheterization. Such procedures can include, for example, one or more of, tests typically applied prior to catheterization and/or reducer delivery, various cardiac function measurements, determination that the patient suffers from ischemic heart disease, determination of angina class, performing electrocardiographgy, full blood work, functional and/or perfusion mapping (e.g., using nuclear medicine imaging techniques such as PET, Thallium or Technetium), to determine pre-procedure perfusion state, echo-cardiography, echo-dobutamin, estimation of micro-cardiological perfusion, Millar catheterization and physiological measurements, such as cardiac output, pulse pressure, left ventricular end-diastolic pressure and stroke volume, left arterial pressure, SVO_2% in the right atrium and/or coronary sinus, intra-myocardial pressure and/or stress testing, such as tread-mill exercise testing. Optionally an imaging technique (e.g., ultrasound, MRI, angiography, or CT) is used to determine the size and/or shape of the coronary sinus and/or other coronary veins.

Just prior to the catheterization, the patient is optionally attached to various monitoring equipment, for example, one or more of ECG (especially to detect and/or monitor one or more of heart rate, ischemic changes, rate disturbances and/or ST segment changes), an arterial line for measuring blood pressure, a pulse oxymeter, a body thermometer and/or apparatus for tracking blood gases.

first end 526 and a second end 527; and a tenth member having a first end 529 and a second end 530. The first end 514 of the fifth member 513 is joined to the second end 503 of the first member 501 at second junction point 542, the second end 515 of the fifth member 513 is joined to the second end 518 of the sixth member by a curved member 539 to form a third loop 532, the first end 517 of the sixth member 516 is joined to the first end 520 of the seventh member 519 by a fifth curved member 548, the second end 521 of the seventh member 519 is joined to the second end 524 of the eighth member 522 at third junction point 540 to form a fourth loop 533, the first end 523 of the eighth member 522 is joined to the first end 526 of the ninth member 525 by a sixth curved member 549, the second end 526 of the ninth member 525 is joined to the second end 530 of the tenth member 528 by a seventh curved member 541 to form a fifth loop 534, and the first end 529 of the tenth member 528 is joined to the second end 512 of the fourth member 510. The third loop 532 defines a third angle 545. The fourth loop 533 defines a fourth angle 546. The fifth loop 534 defines a fifth angle 547.

[0031] In the embodiment shown in Fig. 4, the first member 501, the third member 507, the sixth member 516, the eighth member 522, and the tenth member 528 have substantially the same angular orientation to the longitudinal axis of the stent and the second member 504, the fourth member 510, the fifth member 513, the seventh member 519, and the ninth member 512 have substantially the same angular orientation to the longitudinal axis of the stent. In the embodiment shown in Figure 4, the lengths of the first, second, third and fourth members 501, 504, 507, 510 are substantially equal. The lengths of the fifth, sixth, seventh, eighth, ninth and tenth members 513, 516, 519, 522, 525, 528 are also substantially equal. Other embodiments where lengths of individual members are tailored for specific applications, materials of construction or methods of delivery are also possible, and may be preferable for them.

[0032] Preferably, the first, second, third, and fourth members 501, 504, 507, 510 have a width that is greater than the width of the fifth, sixth, seventh, eighth, ninth, and tenth members 513, 516, 519, 522, 525, 528 in that cell. The differing widths of the first, second, third, and fourth members and the fifth, sixth, seventh, eighth, ninth, and tenth members with respect to each other contribute to the overall flexibility and resistance to radial compression of the cell. The widths of the various members can be tailored for specific applications. Preferably, the fifth, sixth, seventh, eighth, ninth, and tenth members are optimized predominantly to enable longitudinal flexibility, both before and after expansion, while the first, second, third, and fourth members are optimized predominantly to enable sufficient resistance to radial compression to hold a vessel open. Although specific members are optimized to predominantly enable a desired characteristic, all the portions of the cell interactively cooperate and contribute to the characteristics of the stent.

[0033] Figures 5 and 6 show a pattern and an expanded view of one cell of an embodiment of the present invention which is specially adapted for a stent made of stainless steel. The pattern is similar to the pattern of Figures 3 and 4, and the same reference numerals are used to indicate the generally corresponding parts.

[0034] In this embodiment of the invention, for example, the second loops 531 are made stronger by shortening the third and fourth members 507, 510. This helps assure that the second loops do not "flare out" during delivery of the stent through tortuous anatomy. This "flaring out" is not a concern with NiTi stents which are covered by a sheath during delivery.

[0035] Furthermore, the length of the members in this embodiment may be shorter than the length of the corresponding members in the embodiment illustrated in Figures 3 and 4. Typically, the amount of strain allowed in a self-expanding NiTi stent may be around 10%. In a stainless steel stent, the amount of strain allowed typically may be 20% or greater. Therefore, to facilitate stents made of NiTi and stents made of stainless steel expanding to comparable diameters, the members of the NiTi stent may be longer than the members of a stainless steel stent.

[0036] Figure 7 illustrates another aspect of the present invention. The stent of Figure 7 is also constructed from orthogonal meander patterns 301, 302. The meander patterns form a series of interlocking cells 50, 700 of two types. The first type of cell 50 is taught by U.S. Patent No. 5,733,303. These cells are arranged so that they form alternating bands 704 of first type of cells 50 and bands 706 of the second type of cells 700.

[0037] As seen in Figure 8 and particularly with respect to the cell labeled for ease of description, each of the ' 303 cells 50 has a first longitudinal apex 100 and a second longitudinal end 78. Each cell 50 also is provided with a first longitudinal end 77 and a second longitudinal apex 104 disposed at the second longitudinal end 78. Each cell 50 also includes a first member 51 having a longitudinal component having a first end 52 and a second end 53; a second member 54 having a longitudinal component having a first end 55 and a second end 56; a third member 57 having a longitudinal component having a first end 58 and a second end 59; and a fourth member 60 having a longitudinal component having a first end 61 and a second end 62. The stent also includes a first loop or curved member 63 defining a first angle 64 disposed between the first end 52 of the first member 51 and the first end 55 of the second member 54. A second loop or curved member 65 defining a second angle 66 is disposed between the second end 59 of the third member 57 and the second end 62 of the fourth member 60 and is disposed generally opposite to the first loop 63. A first flexible compensating member (or a section of a longitudinal meander pattern) 67 having curved portion and two legs with a first end 68 and a second end 69 is disposed between the first

performed, for example, one or more of Atrium and chamber pressures, LVEDP, functional tests such as echo-dobutamin and/or perfusion tests. Optionally, Heparin is provided and an ACT (Activated Clotting time) test is performed.

At 712, a guide catheter is inserted into the coronary sinus. In some delivery methods, no separate guide catheter is needed. Before inserting the reducer, various measurements may be performed, for example, a base-line coronary sinus pressure (e.g., using a pressure transducer at the end of the catheter), an angiographic mapping of the coronary sinus, for example to assist in determining what size reducer to use and/or a test obstruction of the coronary sinus, for example to assist in determining a desired narrowing dimension of the reducer that will achieve a desired pressure increase and/or to detect possible side effects in the patient of such a pressure increase.

At 714, a guide sheath is inserted over the catheter to the coronary sinus. However, alternative insertion methods can be used, for example, guiding reducer 100 over a guide wire or along a monorail guide wire. The reducer may be provided with the sheath or it may be inserted through the sheath after the sheath is in place. The reducer may be guided to the coronary sinus. Alternatively or additionally, a suitably sized reducer may be inserted in one or more coronary veins.

At 716, the reducer is deployed. In an exemplary embodiment of the invention, deployment comprises delivering the reducer and expanding the reducer (e.g., self-expanding or balloon-expanded).

At 718, various measurements are optionally performed, for example, coronary sinus pressures and cardiac functions (e.g., as noted above). Optionally, as described below, the narrowing diameter is changed in response to results of the measuring. Optionally, an image is acquired to ensure the reducer is positioned correctly. Optionally, a measurement of the coronary sinus pressure is made to ensure that the resulting increase in pressure (e.g., by 20 mmHg or 30 mmHg) does not go beyond the holding capacity of the vein or some other safety number (e.g., 50 mmHg). If the pressure exceeds the holding capacity, the narrowing may be enlarged, to reduce the pressure differential. It should be noted that such measurements may be performed before, during and/or after a corresponding arterial treatment that may be performed concurrently with the venous treatment.

At 720, the delivery system is retracted. Optionally, various measurements (e.g., cardiac function) are performed a short-time after deployment, for example, after half an hour.

It is expected that one or more of the following effects is detected (at once and possibly to a greater extent after some delay): retrograde increase in coronary sinus pressure, with a possible associated retrograde flow, improvement of perfusion in some ischemic areas, reduction in venous O_2 saturation (e.g., greater extraction of Oxygen by the cardiac muscle) and/or increase of intra-myocardial pressure, as an indication of possible redistribution of blood supply in the heart. Alternatively or additionally, functional improvements may be viewed, for example, an improvement in segmental contraction, which can be seen using ECHO methods.

At 722, an optional short term follow-up, for example after a few hours, days or weeks is performed. At 724, an optional long term follow-up, for example, after a few months or years is performed. In an exemplary embodiment of the invention, follow-ups are performed after one week, two weeks one month, three months, six months and then yearly. Such follow-up may include, for example, tracking of angina class, treadmill stress test, perfusion estimation (e.g., using SPECT), functional estimation, for example, using echo-dobutamin and/or any other typically applied tests.

It is expected that after a few weeks, the myocardial perfusion and intra-myocardial pressure will increase and redistribution of myocardial blood flow will improve, even beyond the immediate result of the insertion of reducer 100. Possibly, the auto-regulation mechanism of the coronary flow will start working again, by the pressure in the coronary arteries increasing beyond the threshold for activation of the autoregulation mechanism and/or revascularization should start. After a few months, revascularization is expected to be well established, and significantly improve the clinical picture.

Optionally, the above procedure is varied by first placing a stent or a graft into the coronary sinus and mounting the reducer inside the stent or the graft.

Optionally, the reducer includes an integral blood pressure sensor, or a separate small blood pressure monitor is implanted, for example as described in US patent 6,053,873, in WO 00/32092, in WO 99/34731 and in US patent 6,159,156, the disclosures of which are incorporated herein by reference. One or more transducers are optionally implanted, for example, to measure a pressure differential across the reducer.

Reducer 100 may be varied in various manners. It should be noted, that when placing a reducer in a blood vessel it is generally desirable that the flow through the reducer be smooth. Alternatively, the flow may be made turbulent, for the express purpose of reducing the flow rate through the reducer.

the function of reducer 800 and will allow a new reducer to be implanted within reducer 800, at a later time.

Alternatively, as shown, two sizes of slits 806 are provided, with the degree of resistance to deformation being determined by the sizes and/or relative sizes of the slits.

Figs. 9A-9F illustrate various reducer variations, in accordance with exemplary embodiments of the invention. While a sigmoid-like flaring is shown, a linear or other flaring design may also be provided.

Fig. 9A shows a reducer 900 with having a narrowing 902 and only a single flared out portion 904. Narrowing 902 may point upstream or down stream. One potential advantage of this design, is that the delivery system is less likely to get caught inside narrowing 902. Another potential advantage is that a completely obstructing implant can be provided. In an exemplary embodiment of the invention, however, even such a completely obstructing implant has smooth sides, to prevent damage to the coronary sinus. Possibly, the outer diameter of the completely obstructing implant or a nearly complete reducer is increased beyond that of the coronary sinus, to prevent dislodgment of the implant. Alternatively or additionally, one or more barbs on the outside of the implant may be provided. Optionally, a cone shaped reducer is provided with one or more openings for blood flow on the face of the cone, rather than at its apex as shown.

Alternately to a plain reducer, the narrowing may be a valve, for example, a valve which opens, to a full or partial diameter, after a suitable pressure is achieved in the coronary sinus distal from the right atrium. For example, a leaflet valve or other type of vascular valve as known in the heart may be provided.

Fig. 9B shows an alternative reducer 910, with two narrowings 912 and 916 sandwiching a flared out portion 914 between them. Optionally, the different narrowings have a different inner diameter. Optionally, the narrowings are selectively expanded using a balloon to achieve a desired pressure profile.

Fig. 9C shows an alternative reducer 920 with three narrowings 922, 926 and 929 and two flared out portions 924 and 928 between the narrowings.

Fig. 9D is an example of an asymmetric reducer 930, in which one flared out portion 932 has a smaller diameter than a second flared out portion 936, but larger than an intermediate narrowing portion 934. Such a reducer may be useful, for example, for veins that change in size along their length, such as the coronary sinus right next to the right atrium.

In Fig. 9E, a reducer 940 is not symmetric around its axis, with one flared out portion 946 being distorted relative to an axis defined by a second flared out portion 942 and a narrowing portion 944.

Optionally, the reducer is curved. In an exemplary embodiment of the invention, asymmetric or curved reducers include special markings, for example, radio-opaque or radio-transparent areas, to assist correct orientation of the reducer in a blood vessel.

Fig. 9F shows a reducer 950, in which a narrowing section 954 is a sleeve, for example, formed of a flexible graft material, such as Dacron or GoreTex. Reducer 950 further comprises at least one of two outer rings 952 and 956 that serve to anchor reducer 950 in the blood vessel. A potential advantage of using a sleeve is that it can bend to conform to the vein geometry and/or dynamics. Other reducer designs can also bend. Optionally, the graft material is elastic, so it can serve as a pressure limiting valve, to better control coronary sinus pressure. Optionally, a constraining ring is provided on the outside of section 954, to restrict the lumen of reducer 950. Optionally, the ring is placed on reducer 950 during the procedure, to achieve a desired narrowing effect. Alternatively or additionally, the ring is expandable, for example using a balloon, to allow controlling the narrowing of reducer 950. Optionally, the ring is sutured to narrowing section 954. Optionally, section 954 is stiffened, for example, using a wire, as known in the art of stent-grafts.

Optionally, the above various reducers use a delivery system with a matched balloon form (e.g., different diameters of inflation at different parts). Alternatively, a single balloon with controllable inflation (e.g., a central part and a plurality of fingers) is provide, in which the balloon is placed inside the reducer at a certain axial position and inflated to further expand that section. Alternatively, different axial sections of the reducer have different resistance, elasticity, plasticity and/or other mechanical properties.

Optionally, the reducer is adapted to release one or more molecules into the blood flow, for example, angiogenesis causing molecules, adhesion enhancing molecules (e.g., for adhesion to the vein wall), anti-coagulation drugs, growth factors, DNA carriers (e.g., liposomes, plasmids), hormones, and/or other molecules as known in the art. In an exemplary embodiment of the invention, the release is towards the vessel wall and/or towards the blood flow. Optionally, the release is selectively in the part of the flow before the narrowing or after the narrowing, to take advantage or to avoid backflow caused by the reducer. Various release mechanisms are known in the rat and may be used, for example, using a coated

reducer, a porous reducer, a reducer with a drug chamber or a reducer that includes a channel between the reducer and the vein wall for holding the drug.

A reducer, similar to that of Fig. 3, has been tested on animals (pigs), using the following procedure.

(a) Anti-Trandelburg of the animal, to increase venous return in the Jugular.

(b) Clearing an area over a vein (e.g., Jugular, Femoral, Subclavian).

(c) Insert F6 sheath directly into vein.

(d) Provide heparin 2500 units.

(e) Insert a catheter to the coronary sinus.

(f) Insert Amplaz super stiff guide of 180 mm or 200 mm to coronary sinus.

(g) Attempt to insert 3.5 mm outer diameter reducer through an IVC filter sheath.

(h) Pass a balloon through a 40 cm or 60 cm arrow sheath. inflate and deflate twice and then place reducer on the deflated balloon, and check for stability.

(i) Insert IVC filter sheath to coronary sinus, as distal as possible and pass reducer through sheath. If reducer moves, inflate balloon a bit. Then position reducer in coronary sinus.

(j) Check ACT.

(k) Advance reducer so that it leaves sheath arrow and inflate balloon to fix reducer in place.

(l) Remove balloon (possibly sucking out fluid from balloon using a syringe). Twist the balloon.

(m) If arrow sheath gets stuck on narrowing section of reducer, try rotating sheath and/or using IVC filter sheath as a contra.

(n) If reducer did not fit in step (g), put in a peel away banana sheath.

(o) Insert reducer of (h) through banana sheath. Since banana is 14F and sheath arrow is 10F, there may be some bleeding. Inflate balloon if reducer moves.

(p) Do (i)-(l)

(q) Is sheath arrow gets stuck in narrowing section of reducer, take out banana sheath, cut proximal end of balloon and sheath arrow and insert IVC filter sheath for use as a contra (as in (m).

The effect of inserting reducer 100 in four animals (pigs), was estimated to be an average increase in coronary sinus mean pressure from 7.0 mmHg to 24.6 mmHg. These measurements were made with a Swan-Ganz catheter including a narrowing balloon mounted on the catheter to emulate the effect of reducer 100. The amount of narrowing was estimated to be between 70% and 80% based on an angiogram using injected contrast

herein may be adapted for use with prior art devices, in accordance with other exemplary embodiments of the invention. The particular geometric forms and measurements used to illustrate the invention should not be considered limiting the invention in its broadest aspect to only those forms. Although some limitations are described only as method or apparatus limitations, the scope of the invention also includes apparatus designed to carry out the methods and methods of using the apparatus.

Also within the scope of the invention are surgical kits, for example, kits that include sets of delivery systems and reducer implants. Optionally, such kits also include instructions for use. Measurements are provided to serve only as exemplary measurements for particular cases, the exact measurements applied will vary depending on the application. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

CLAIMS

1. A reducer for insertion in a blood vessel, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter at least 20% greater than said first diameter,

wherein said reducer is formed of a material and has a geometry that does not cause coagulation of blood in its vicinity.

2. A reducer according to claim 1, wherein said reducer is operative to increase a coronary artery blood pressure when inserted in a coronary vein.

3. A reducer according to claim 1, wherein said reducer is operative to modify a coronary artery blood flow distribution when inserted in a coronary vein.

4. A reducer according to claim 1, wherein said reducer is operative to increase a coronary sinus blood pressure when inserted in a coronary sinus.

5. A reducer according to claim 1, wherein said reducer is operative to increase an intra-myocardial perfusion when inserted in a coronary sinus.

6. A reducer according to any of claims 1-5, wherein said flared section includes at least one area adapted to contact a wall of a vein.

7. A reducer according to claim 6, wherein said area is made large enough to prevent damage to the wall.

8. A reducer according to claim 7, wherein said area has an axial extent of at least 2 mm.

9. A reducer according to claim 7, wherein said area has an axial extent of at least 4 mm.

10. A reducer according to any of claims 1-9, wherein said flared section has an outside edge.

11. A reducer according to claim 10, wherein said outside edge lies on a single plane.

12. A reducer according to claim 10 or claim 11, wherein said outside edge is defined by a plurality of elongate sections that cooperate to define a maximal rim for said reducer.

13. A reducer according to any of claims 10-12, wherein said outside edge is smooth.

14. A reducer according to any of claims 10-13, wherein said outside edge is curved inwards towards an axis of said reducer.

15. A reducer according to any of claims 10-14, wherein said outside edge is coated with a soft material.

16. A reducer according to any of claims 1-15, wherein said reducer doesn't cause turbulence inside a lumen defined by said narrowed section and said flared section.

17. A reducer according to any of claims 1-16, wherein said narrowed section comprises a ring segment having a different surface design from flared section.

18. A reducer according to any of claims 1-17, wherein said narrowed section comprises a solid ring.

19. A reducer according to any of claims 1-17, wherein said narrowed section comprises an array of cell elements.

20. A reducer according to any of claims 1-19, wherein said reducer is expanded, after insertion, from an unexpanded configuration to an expanded configuration.

21. A reducer according to claim 20, wherein said flared section is plastically deformable to provide said configuration change.

22. A reducer according to claim 20, wherein said flared section is self-expanding to provide said configuration change.

23. A reducer according to any of claims 20-22, wherein said narrowed section self-expanding to provide said configuration change.

24. A reducer according to any of claims 20-22, wherein said narrowed section is plastically deformable to provide said configuration change.

25. A reducer according to claim 20, wherein said narrowed section does not expand.

26. A reducer according to claim 20, wherein said narrowed section is further expandable after said reducer is in said expanded configuration.

27. A reducer according to any of claims 1-26, comprising a ring mounted outside of said narrowed section, said ring defining a maximal diameter of said narrowed section.

28. A reducer according to any of claims 1-27, wherein said narrowed section is formed of a pliable material.

29. A reducer according to any of claims 1-27, wherein said reducer is formed of at least one of an elastic material, a shape-memory material and a super-elastic material.

30. A reducer according to any of claims 1-29, wherein different parts of said reducer have different degrees of resistance to deforming.

31. A reducer according to claim 30, wherein said narrowed section has a greater resistance to deformation than said flared section.

32. A reducer according to claim 30, wherein a rim area of said flared section has a greater resistance to deformation than an adjacent part of said flared section.

33. A reducer according to any of claims 1-32, wherein said narrowed section has an axial extent of between 1 mm and 5 mm.

34. A reducer according to any of claims 1-33, wherein said reducer has an axial extent of between 10 mm and 30 mm.

35. A reducer according to any of claims 1-34, wherein said narrowed section has a cross-sectional area of less than 70% of a maximum cross-sectional area of said flared section.

36. A reducer according to any of claims 1-34, wherein said narrowed section has a cross-sectional area of less than 50% of a maximum cross-sectional area of said flared section.

37. A reducer according to any of claims 1-34, wherein said narrowed section has a cross-sectional area of less than 40% of a maximum cross-sectional area of said flared section.

38. A reducer according to any of claims 1-34, wherein said narrowed section has a cross-sectional area of less than 30% of a maximum cross-sectional area of said flared section.

39. A reducer according to any of claims 1-34, wherein said narrowed section has a cross-sectional area of less than 20% of a maximum cross-sectional area of said flared section.

40. A reducer according to any of claims 1-39, wherein said flared section has an axial extent of between 4 mm and 10 mm.

41. A reducer according to any of claims 1-40, wherein said reducer is adapted for insertion in a human coronary sinus.

42. A reducer according to any of claims 1-41, wherein said reducer is adapted for insertion in a human coronary vein.

43. A reducer according to claim 41 or claim 42, wherein said adaptation is by size.

44. A reducer according to any of claims 1-43, wherein said at least one flared section comprises at least two flared sections.

45. A reducer according to any of claims 1-44, wherein said reducer describes an hourglass figure.

46. A reducer according to any of claims 1-45, wherein said flared section is dense, to reduce blood flow therethrough.

47. A reducer according to any of claims 1-46, wherein said flared section is coated, to reduce blood flow therethrough.

48. A reducer according to any of claims 1-47, wherein said reducer is formed of a soft material, to reduce contact force against an enclosing vessel wall.

49. A reducer according to any of claims 1-48, wherein said reducer is operative to release a slow release molecule after it is deployed.

50. A reducer according to any of claims 1-49, wherein said reducer has an outside surface adapted to attach to a wall of a vein.

51. A reducer according to any of claims 1-50, wherein said narrowed section comprises a valve.

52. A reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter at least 20% greater than said first diameter,

wherein said reducer is adapted to be plastically deformed from a first configuration in which said reducer is unexpanded to a second configuration in which said reducer is expanded.

53. A reducer according to claim 52, wherein said narrowing section has a length of at least 10% of a total axial length of said reducer.

54. A reducer according to claim 52, wherein said narrowing section has a length of at least 20% of a total axial length of said reducer.

55. A reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter greater than said first diameter,

wherein said reducer is adapted to contact a vein at said flared section.

56. A reducer according to claim 55, wherein said adaptation comprises forming said flared section to reduce a probability of damage to said vein.

57. A reducer according to claim 55, wherein said adaptation comprises forming said reducer of a soft material to reduce a contact force between said reducer and said vein.

58. A reducer according to claim 55, wherein said reducer is adapted to cause coagulation in an area defined between said reducer and a wall of said vein.

59. A reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter at least 20% greater than said first diameter,

wherein said flared section is resistant to blood flow across a wall of said section, such that at least 50% of blood flow through the reducer passes through a lumen defined by said flared section and said narrowed section.

60. A reducer according to claim 59, wherein at least 80% of blood flow through the reducer passes through a lumen defined by said flared section and said narrowed section.

61. A reducer according to claim 59, wherein at least 90% of blood flow through the reducer passes through a lumen defined by said flared section and said narrowed section.

62. A reducer for insertion in a blood vessel having a diameter, comprising:

at least one narrowed section having a first diameter; and

at least one flared section having a diameter substantially greater than said first diameter,

wherein said flared section and said narrowed section cooperate to substantially reduce blood flow through a lumen defined by said sections, relative to flow through a cylinder having a maximal diameter of the flared section

63. A blood vessel reducer delivery kit, comprising:

a guide catheter;

a plastically deformable reducer having an hour-glass figure when deformed and adapted to ride on said catheter; and

a balloon having an inflation profile matching said hour-glass figure.

64. A method of reducer selection, comprising:

determining a desired hemodynamic effect in a coronary vascular system; and

selecting a reducer having a suitable geometry to achieve said desired hemodynamic effect, from a set of reducers of different geometries.

65. A method according to claim 64, wherein said desired effect is at least one of: increase in myocardial perfusion pressure, increase in myocardial pressure, increase in myocardial perfusion duration, increase in coronary artery pressure, redistribution of blood flow in coronary arteries, increase in pressure in a coronary sinus and/or a restarting of a coronary artery autoregulation mechanism.

66. A method of affecting hemodynamic parameters of a coronary system, comprising:

selecting a reducer for reducing a diameter of a coronary vein; and

implanting said reducer in said coronary vein.

67. A method according to claim 66, wherein said coronary vein is a coronary sinus.

68. A kit for reducing blood flow in a venous system, comprising: a plurality of vascular implants, each defining a narrowed section, said plurality of implants including at least two implants with different geometrical properties.

69. A kit according to claim 68, wherein said two implants have different degrees of narrowing.

70. A kit according to claim 68 or claim 69, wherein said two implants have different outer diameters, for matching different coronary veins.

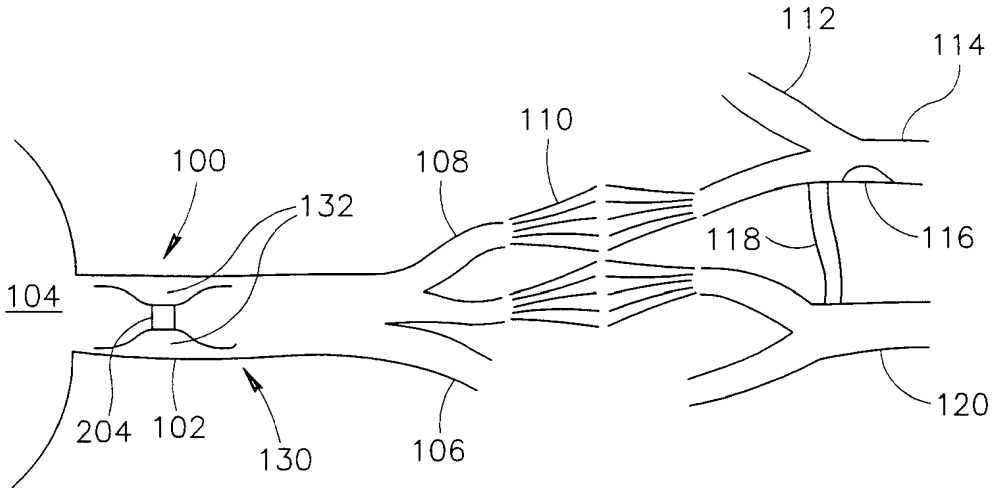
112
114
110
100
108
132
118
116
104
204
102
130
106
120

FIG.1

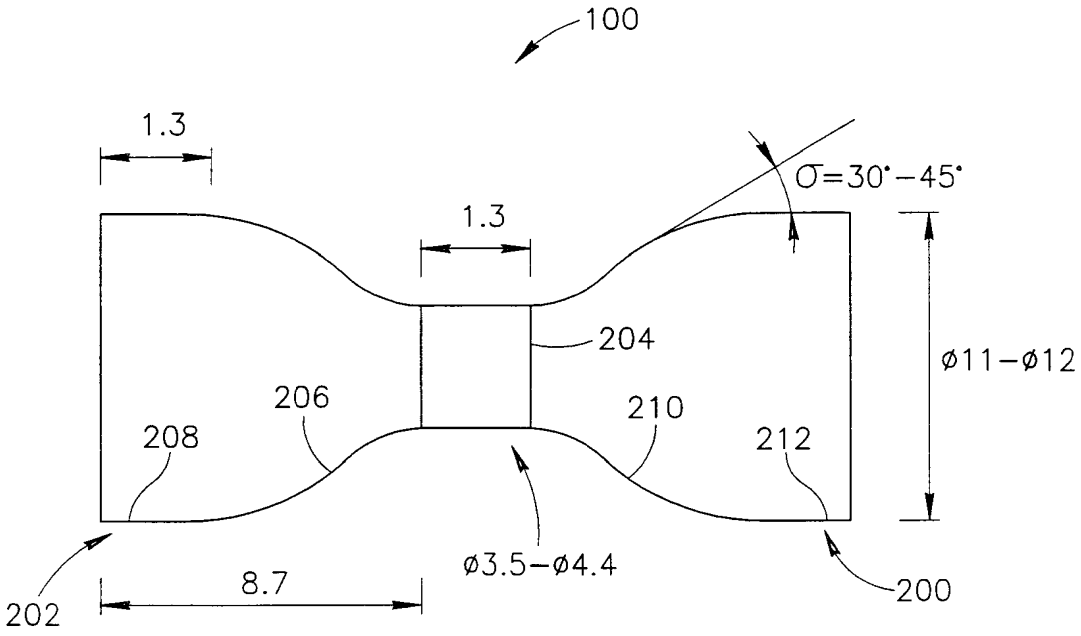
100
1.3
1.3
σ=30°–45°
204
ø11–ø12
206
208
210
212
ø3.5–ø4.4
8.7
202
200

FIG.2

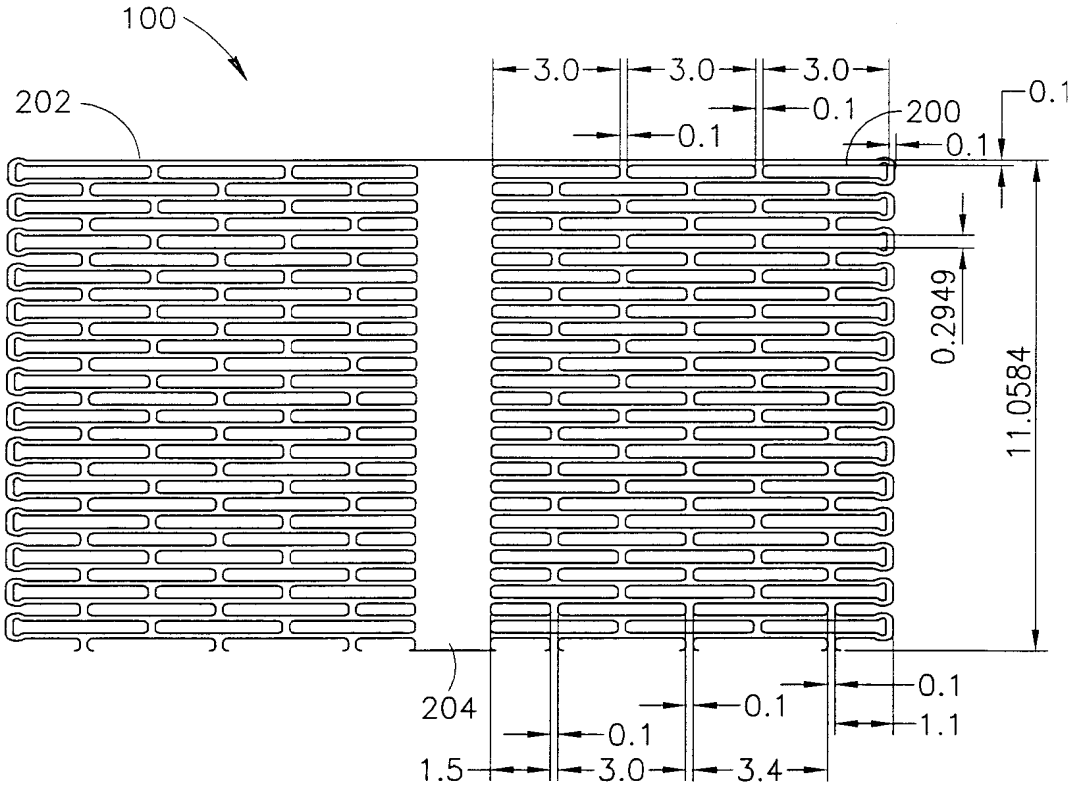
100
202
3.0
3.0
3.0
0.1
0.1
200
0.1
0.1
0.2949
11.0584
204
0.1
0.1
0.1
1.1
1.5
3.0
3.4

FIG.3A

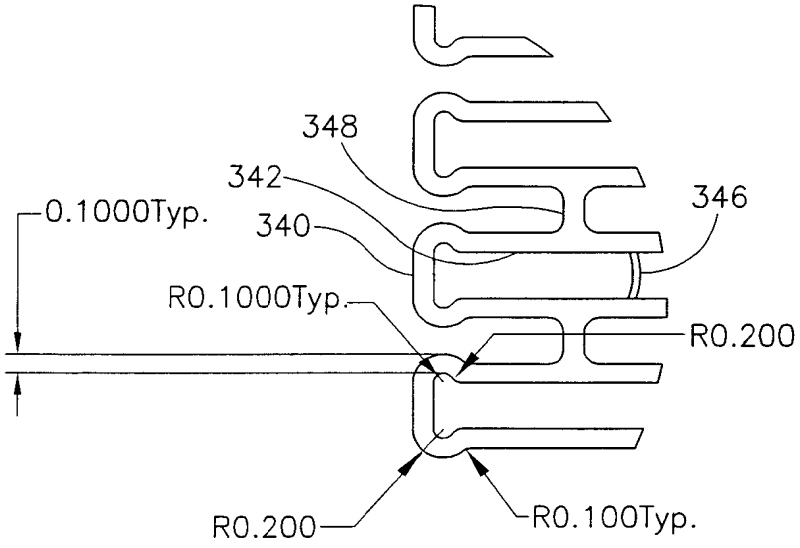
348
342
340
346
0.1000Typ.
R0.1000Typ.
R0.200
R0.200
R0.100Typ.

FIG.3B

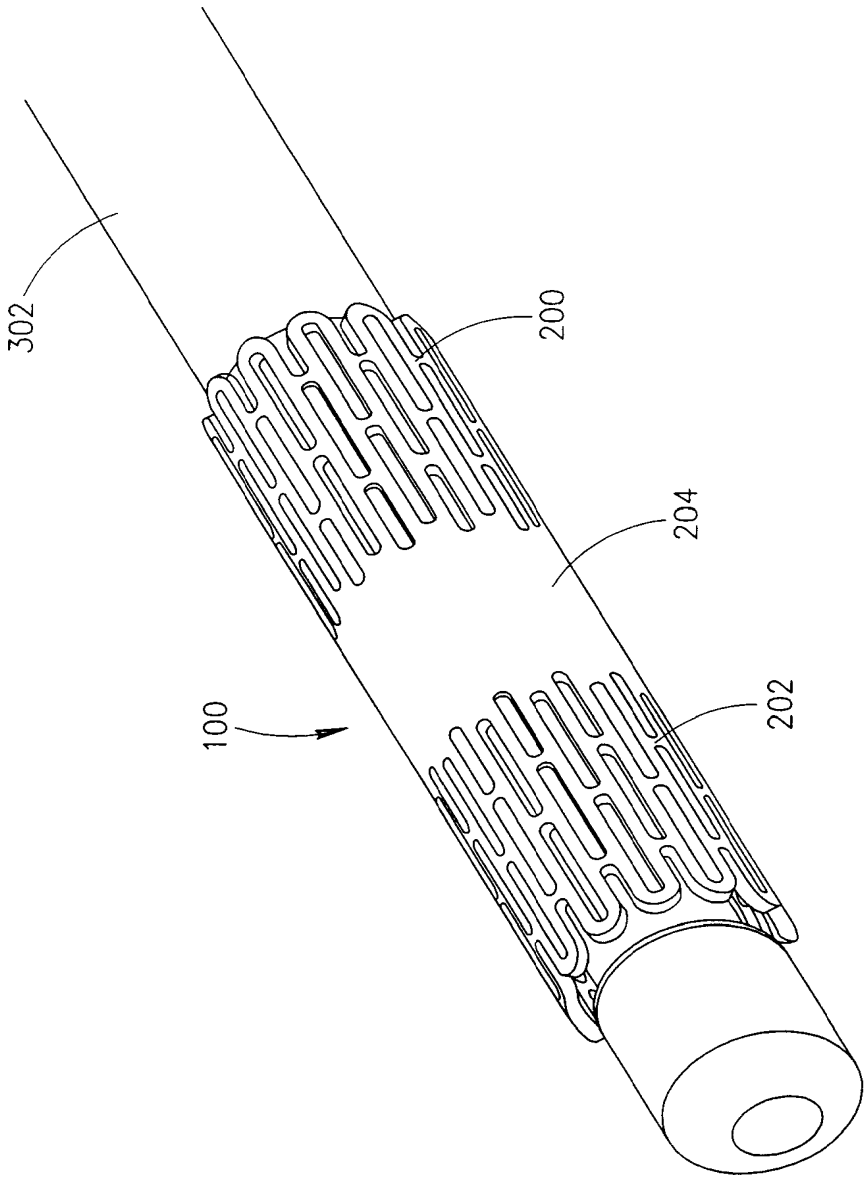

FIG.3C

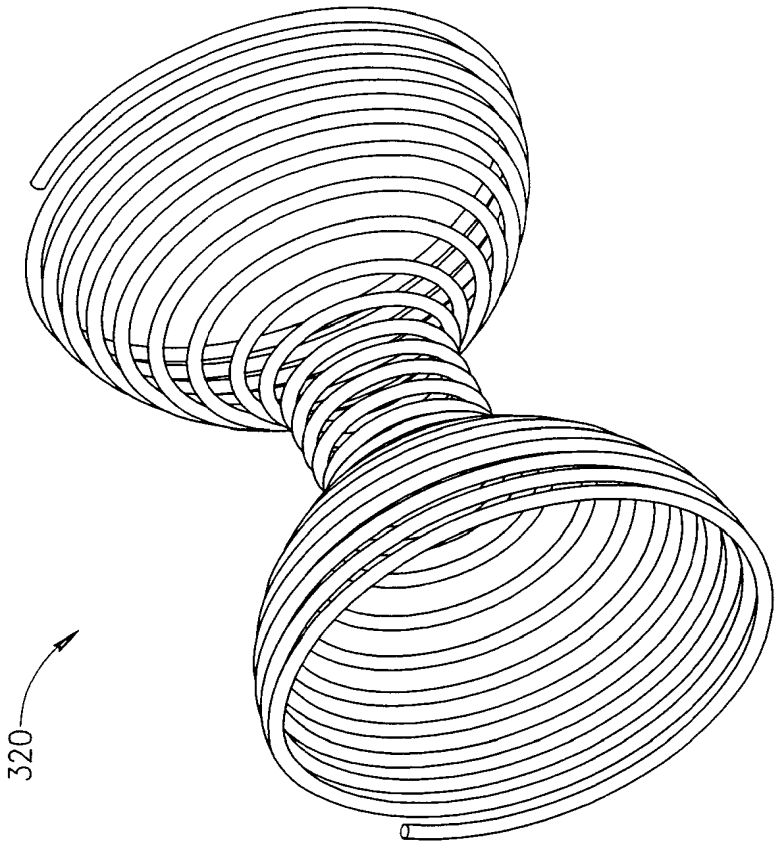

FIG.3D

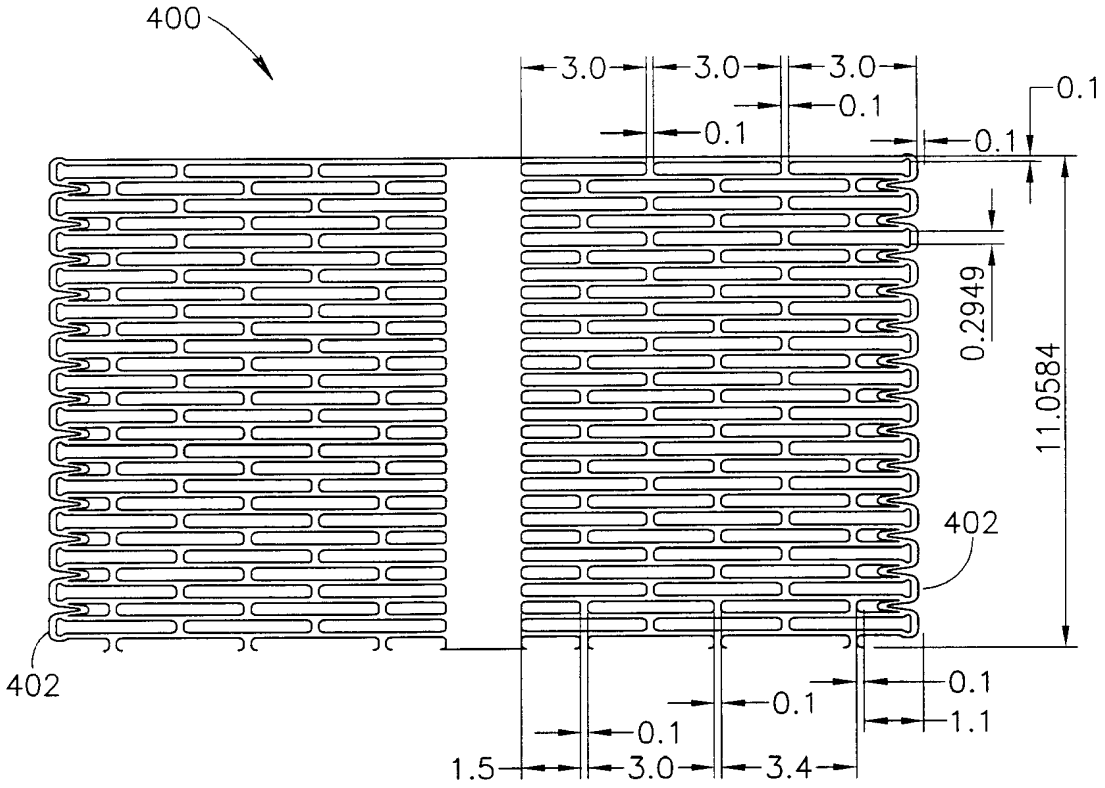
400
3.0
3.0
3.0
0.1
0.1
0.1
0.1
0.2949
11.0584
402
402
0.1
0.1
0.1
1.1
1.5
3.0
3.4

FIG.4A

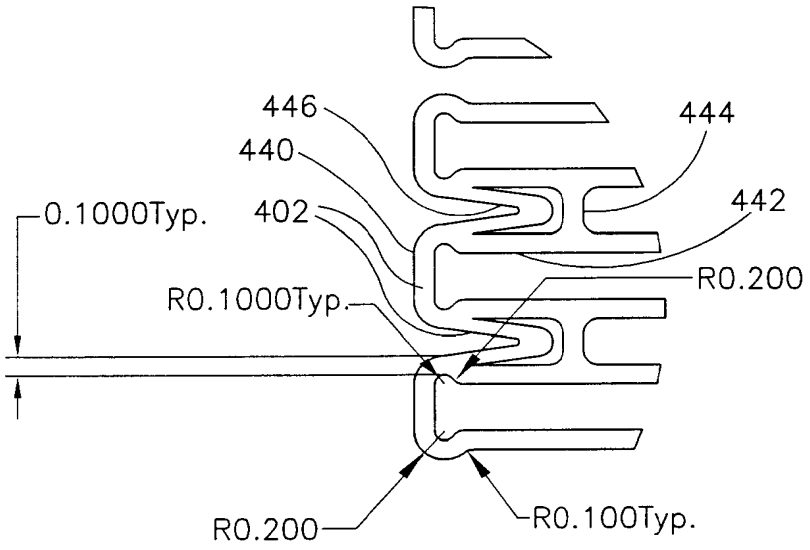
446
444
440
442
0.1000Typ.
402
R0.200
R0.1000Typ.
R0.200
R0.100Typ.

FIG.4B

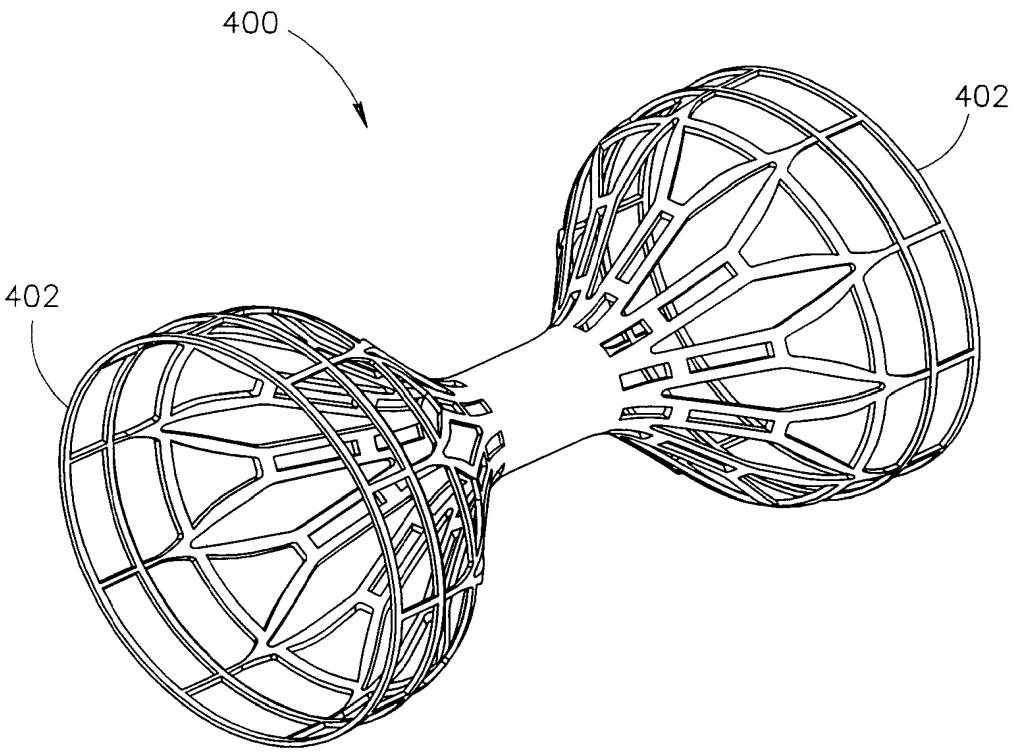

FIG.4C

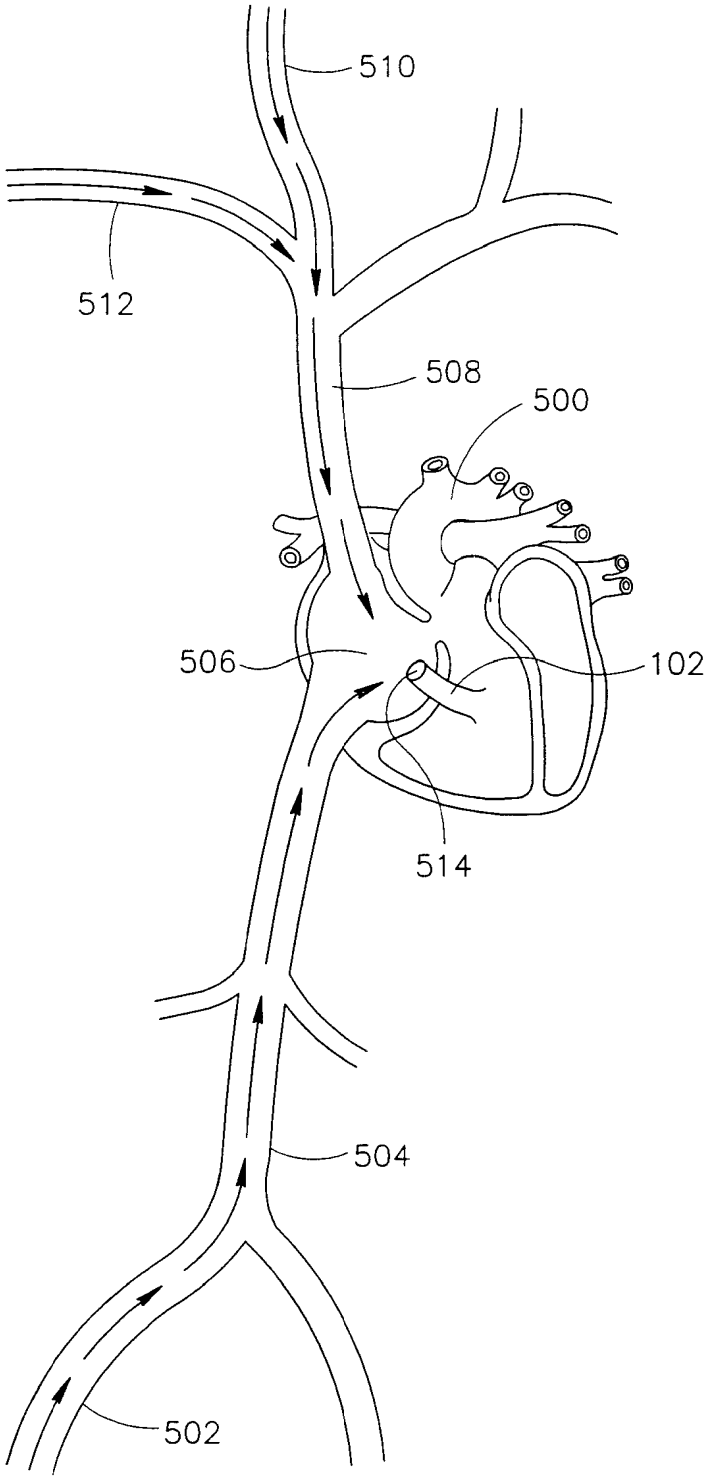

FIG.5

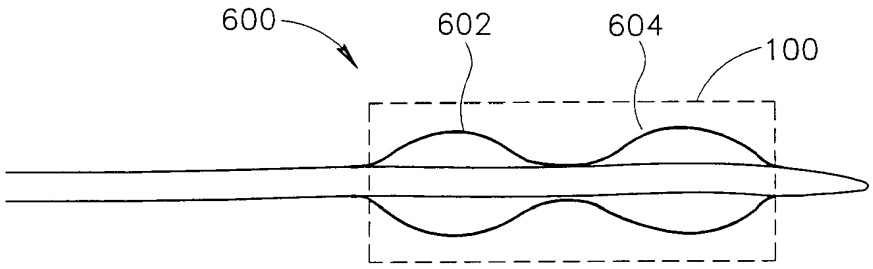

FIG.6A

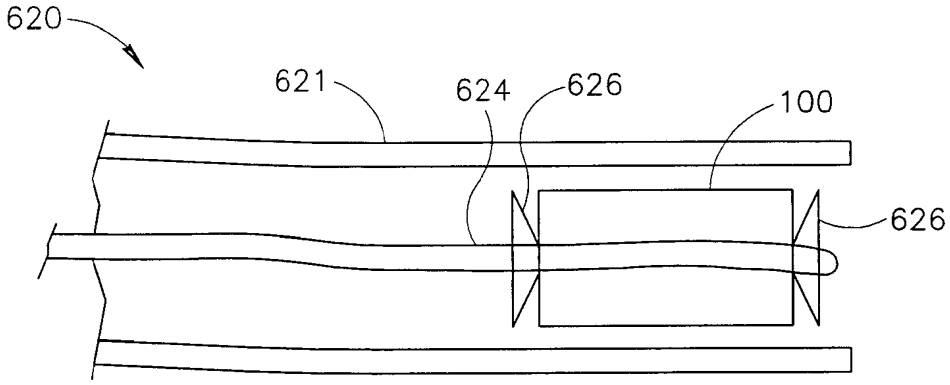

FIG.6B

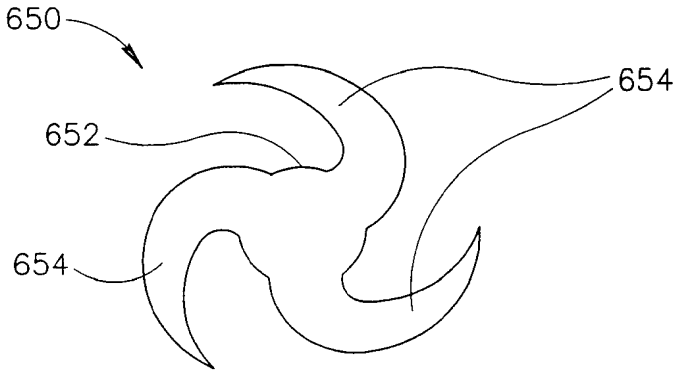

FIG.6C

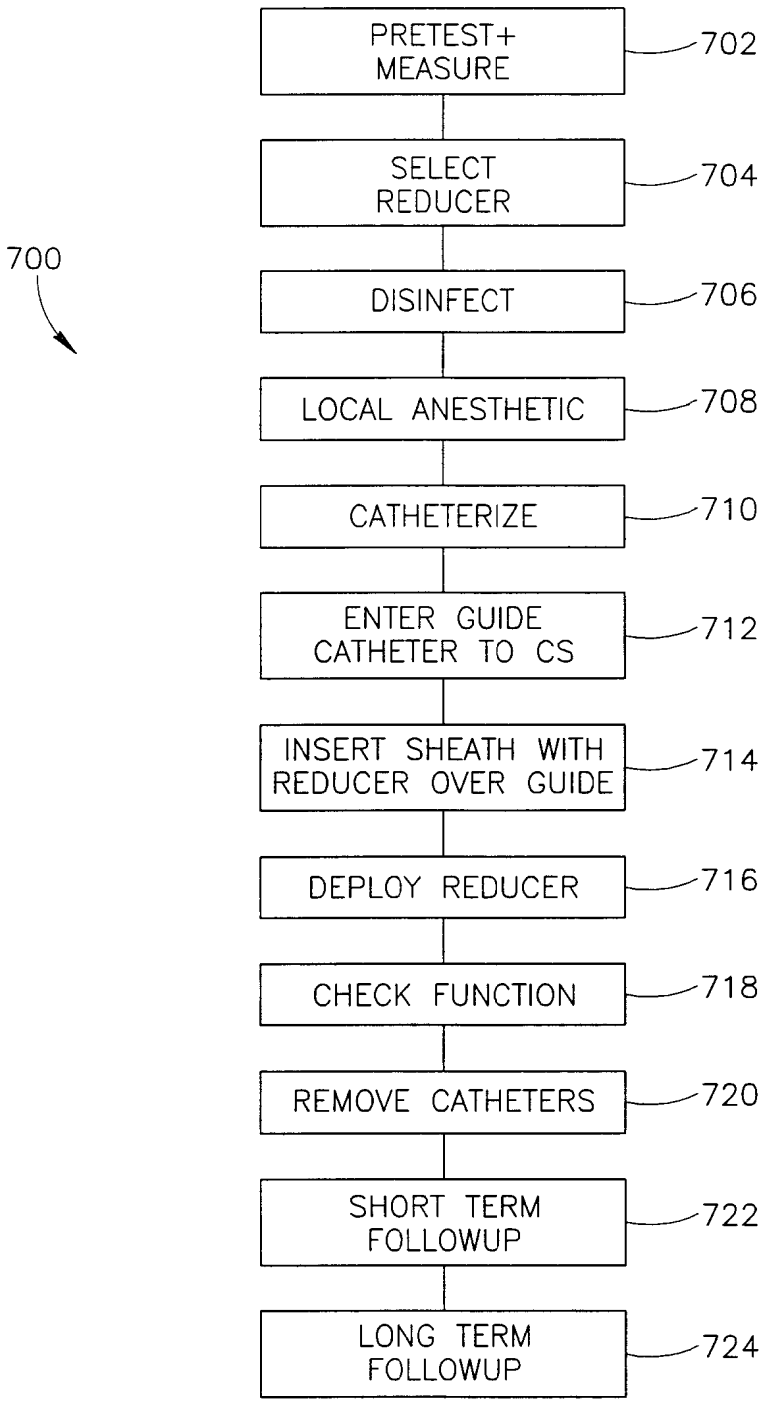
700
PRETEST+ MEASURE
702
SELECT REDUCER
704
DISINFECT
706
LOCAL ANESTHETIC
708
CATHETERIZE
710
ENTER GUIDE CATHETER TO CS
712
INSERT SHEATH WITH REDUCER OVER GUIDE
714
DEPLOY REDUCER
716
CHECK FUNCTION
718
REMOVE CATHETERS
720
SHORT TERM FOLLOWUP
722
LONG TERM FOLLOWUP
724

FIG.7

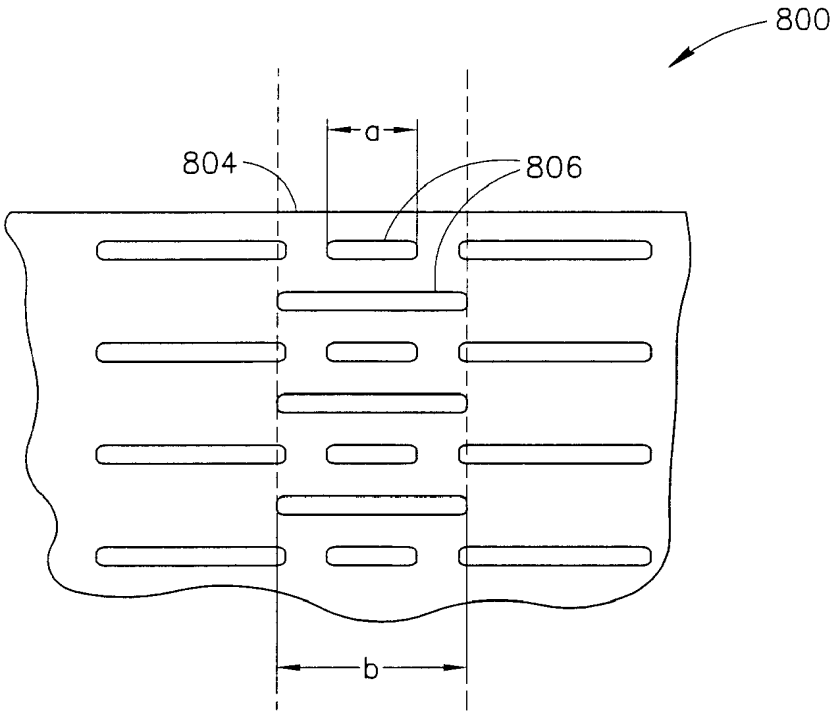

FIG.8

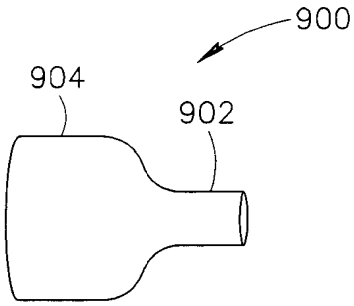

FIG.9A

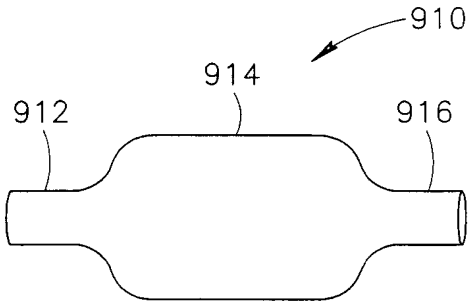

FIG.9B

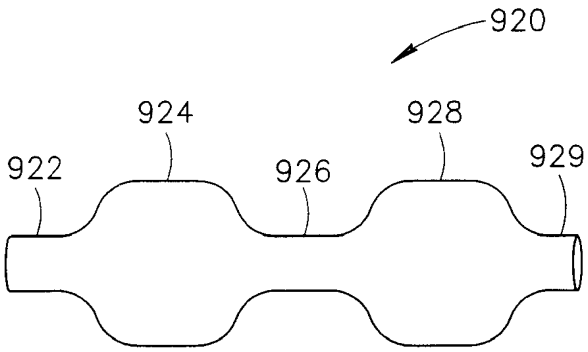

FIG.9C

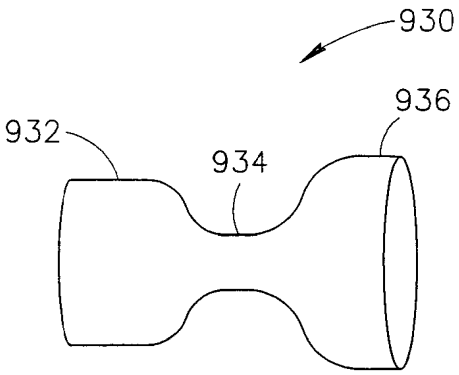

FIG.9D

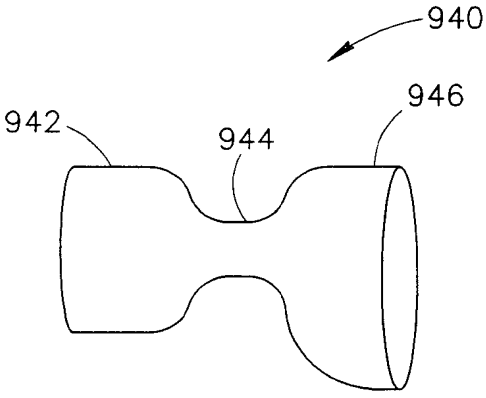

FIG.9E

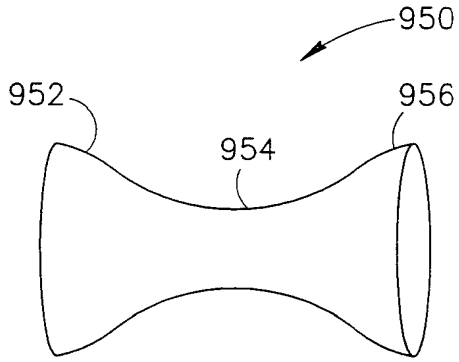

FIG.9F